

Serial No. 10/817,058

Response

Amendments to the Claims

Please amend the claims as follows:

1. (currently amended) A method of reducing the effects of myocardial ischemia in a patient subjected to an ischemic event, comprising the step of:
administering an effective amount of erythropoietin to the patient in a pharmaceutically acceptable formulation, to provide a substantially immediate decrease in the myocardial ischemia.
2. (currently amended) The method of claim 1, wherein the erythropoietin is administered to a the patient to achieve a blood concentration of about 0.5-10 U/ml.
3. (original) The method of Claim 1, wherein a dosage amount of about 50-5,000 U/kg erythropoietin is continuously administered to the patient for about 1-35 minutes to achieve a blood concentration of erythropoietin of about 0.5-10 U/ml.
4. (original) The method of Claim 1, wherein the amount of erythropoietin is effective to provide a blood concentration of about 0.5-10 U/ml within about 1-35 minutes following administration.
5. (currently amended) The method of Claim 1, wherein the step of administering comprises administering the erythropoietin is continuously administered for a period of about 1-20 minutes prior to the ischemic event to achieve a blood concentration of about 0.8-1.5 U/ml.
6. (currently amended) The method of Claim 1, wherein the step of administering comprises administering the erythropoietin is administered to increase the blood level of erythropoietin in the patient to at least about 100 times above a normal level.

Serial No. 10/817,058

Response

7. (currently amended) The method of Claim 6, wherein the step of administering comprises administering the erythropoietin is administered to increase the blood level of erythropoietin in the patient to about 0.8-1.5 U/ml.
8. (original) The method of Claim 1, wherein the erythropoietin is administered parenterally by intravenous, intramuscular, or subcutaneous injection.
9. (original) The method of Claim 1, wherein the decrease in the myocardial ischemia is confirmed by at least one of a decrease in tissue necrosis, maintenance of an organ function, a decrease in cardiac enzyme leakage, a decrease in cardiac contractile protein leakage, maintenance of normal left and right cardiac ventricular cavity pressure, volume and flow, a decrease in cardiac arrhythmias, and a decrease in S-T segment elevation.
10. (original) The method of Claim 1, wherein the erythropoietin is administered at the commencement of reperfusion, during reperfusion, or both.
11. (original) The method of Claim 1, wherein the erythropoietin is administered prior to or during an ischemic event, or both.
12. (original) The method of Claim 11, wherein the ischemic event is due to a disease state selected from the group consisting of a myocardial infarction, pulmonary infarction, stroke, and cerebral infarction.
13. (original) The method of Claim 11, wherein the ischemic event is due to a disease state selected from the group consisting of peripheral vascular occlusive disease, vascular occlusion, pre-natal or post-natal oxygen deprivation, trauma, chronic obstructive pulmonary disease, emphysema, adult respiratory distress syndrome, septic shock, sickle cell crisis, dysrhythmia, and nitrogen narcosis or neurological deficits caused by a heart-lung bypass procedure.

Serial No. 10/817,058

Response

14. (original) The method of Claim 11, wherein the ischemic event comprises a surgical procedure.
15. (original) The method of Claim 14, wherein the surgical procedure comprises a heart surgery.
16. (original) The method of Claim 11, wherein the ischemic event comprises a heart attack.
17. (currently amended) The method of Claim 11, wherein the ischemic event comprises an organ transplant procedure, and the erythropoietin is administered ~~continuously~~ to a donor organ for a period of at least about 15 minutes prior to commencement of the transplant procedure.
18. (original) A method of treating the effects of myocardial ischemia in a patient, comprising the step of: administering an effective amount of erythropoietin to the patient in a pharmaceutically acceptable formulation, wherein a substantially immediate protective effect against myocardial ischemia occurs.
19. (original) A method of reducing the effects of myocardial ischemia in an organ transplant recipient, comprising the step of:
exposing the organ to be transplanted to a pharmaceutically acceptable formulation comprising about 0.5-10 U/ml erythropoietin.
20. (original) The method of Claim 19, wherein the organ is a heart.
21. (original) The method of Claim 19, wherein the step of exposing comprises infusing the formulation into the organ.
22. (currently amended) The method of Claim 19, wherein the ~~exposure step of exposing the organ to erythropoietin is continuous for a period of conducted~~ about 5-30 minutes prior to transplantation.

Serial No. 10/817,058

Response

23. (original) The method of Claim 19, wherein the formulation comprises about 0.8-1.5 U/ml erythropoietin.

24. (currently amended) A method of substantially immediately reducing injury associated with myocardial ischemia and reperfusion in a patient, comprising the step of:

administering an effective amount of erythropoietin to the patient in a pharmaceutically acceptable formulation to provide a blood concentration of about 0.5-10 U/ml within about 1-35 minutes following administration of the formulation.

25. (currently amended) A method of preventing or reducing injury associated with myocardial ischemia in a patient, comprising the step of:

administering an effective amount of erythropoietin to the patient in a pharmaceutically acceptable formulation ~~for an effective time period~~ to activate a protein kinase to prevent or reduce the ischemic injury.

26. (original) The method of Claim 25, wherein the formulation comprises an amount of erythropoietin to provide a blood level of about 0.8-1.5 U/ml erythropoietin within about 1-35 minutes following administration to the patient.

27. (currently amended) A method of preventing or reducing injury associated with myocardial ischemia in a patient, comprising the step of:

administering an effective amount of erythropoietin to the patient in a pharmaceutically acceptable formulation ~~for an effective time period~~ to activate a potassium channel to prevent or reduce the ischemic injury.

28. (original) The method of Claim 27, wherein the formulation comprises an amount of erythropoietin to provide a blood level of about 0.8-1.5 U/ml erythropoietin within about 1-35 minutes following administration to the patient.

Serial No. 10/817,058

Response

29. (original) A method of providing substantially immediate cardioprotection in a patient, comprising the step of:

administering an effective amount of erythropoietin to the patient in a pharmaceutically acceptable formulation, wherein substantially immediate cardioprotection occurs.

30. (original) The method of Claim 29, wherein the substantially immediate cardioprotection occurs within about 1-35 minutes of administration of the erythropoietin.

31. (currently amended) The method of Claim 30, wherein an amount of erythropoietin is administered over an about 1-35 minute period to provide a blood level of about 0.8-1.5 U/ml erythropoietin.

32. (currently amended) A pharmaceutical composition formulated for the treatment of myocardial ischemia, comprising:

a unit dosage of a therapeutically effective anti-ischemic amount of erythropoietin in a pharmaceutically acceptable vehicle wherein administration of the unit dosage to a patient is effective to substantially immediately prevent or reduce myocardial ischemia within about 1-35 minutes of said administration and the patient's hemoglobin level, hematocrit level, or both is increased by less than 10%.

33. (currently amended) The composition of Claim 32, wherein the unit dosage composition comprises a dose amount of about 50-5,000 U/kg erythropoietin.

34. (currently amended) The composition of Claim 32, wherein the composition comprises an amount of erythropoietin to increase the blood level of erythropoietin in a patient to at least about 100 times above a normal level when administered to the patient for a period of about 1-20 minutes of administration.

35. (currently amended) The composition of Claim 32, wherein the composition comprises an amount of erythropoietin to increase the blood level of erythropoietin in a patient to about

Serial No. 10/817,058

Response

100-5,000 mU/ml when administered to the patient for a period of within about 1-35 minutes following administration.

36. (currently amended) The composition of Claim 32, wherein the composition comprises an amount of erythropoietin to activate a protein kinase to prevent or reduce the ischemic injury when administered to the patient for a period of within at least about 1-5 minutes of administration.

37. (currently amended) The composition of Claim 32, wherein the composition comprises an amount of erythropoietin to activate a potassium channel to prevent or reduce the ischemic injury when administered to the patient for a period of within at least about 1-20 minutes of administration.

38. (original) The composition of Claim 32, which is formulated for parenteral administration.

39. (original) The composition of Claim 32, which is formulated for infusion administration.

40. (original) The composition of Claim 32, which is formulated for intranasal administration.

41. (original) The composition of Claim 32, which is formulated for transdermal delivery.

42 (original) The composition of Claim 32, which is formulated for delivery as a suppository.

43. (original) The composition of Claim 32, which is formulated for intraperitoneal delivery.

44. (original) The composition of Claim 32, which is formulated for subcutaneous administration.

Serial No. 10/817,058

Response

45. (original) The composition of Claim 32, which is formulated for intramuscular administration.

46. (currently amended) A pharmaceutical unit dosage form, comprising:
a therapeutically effective anti-ischemic amount of erythropoietin in a pharmaceutically acceptable vehicle such that administering the unit dosage of the erythropoietin to a patient provides a blood level of erythropoietin to substantially immediately reduce myocardial ischemia when administered to a in said patient within about 1-35 minutes of administering the erythropoietin, wherein the patient's hemoglobin level, hematocrit level, or both, does not substantially increase.